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(71) Applicant *(for all designated States except US)*: DURAS TRADING LIMITED [IE/IE]; Kildress House, Pembroke Row, Lower Baggot Street, Dublin 2 (IE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: CLAESSENS, Albert, Louis, Victor, Jozef [BE/BE]; Guldensporenlaan 70 B, B–3530 Houthalen (BE). McDONALD, Austin [IE/US]; 18 Normandie Lane, Raritan, NJ 08869–1004 (US). LIEPOLD, Gerhard [DE/US]; 10 Friar Lane, Watchung, NJ 07060 (US). STOLLENMAIER, Donald [US/US]; 20 Evans Farm Road, Morristown, NJ 07960 (US).

(74) Agent: MACLACHLAN & DONALDSON; 47 Merrion Square, Dublin 2 (IE).

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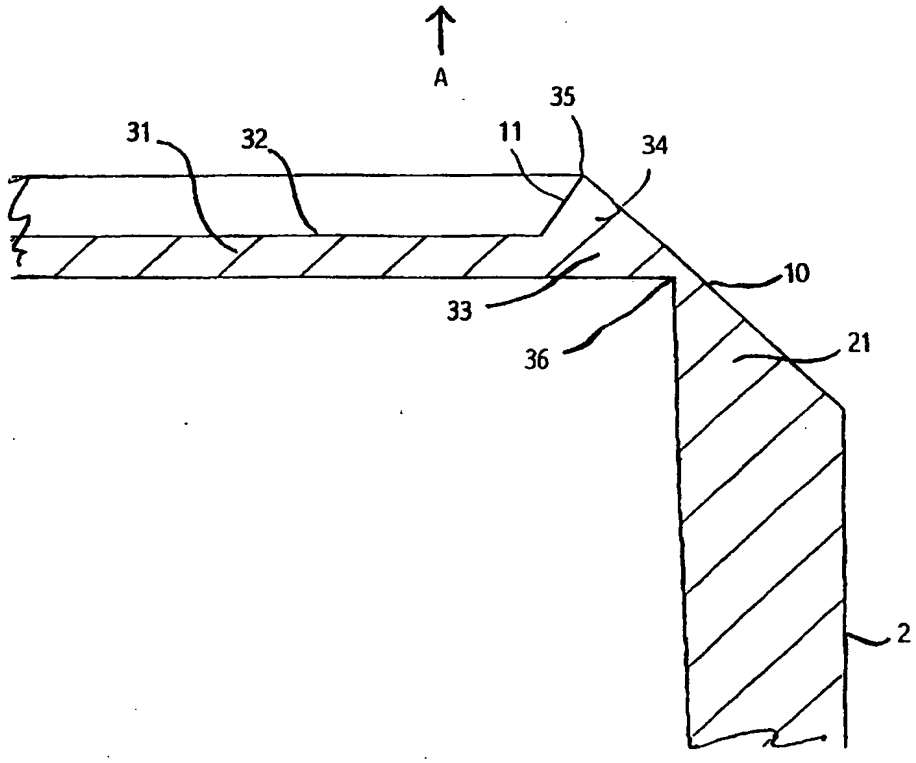
(57) Abstract

A closure (1) for a transportable container used in the transfer of materials to or from an enclosed process area is described. The container docks with a port in a wall of the process area forming a sealed connecting chamber which is sterilised by irradiation. Communication between the interiors of the container and the process area is then established. The closure (1) has a collar (2) and a lid (31), which portions are formed so that all the surfaces which form part of the connecting chamber in use are in the direct line of the sterilising radiation, which is normally ultra–violet or pulsed white light radiation. No relevant surface is shadowed from the radiation. The lid (31) may be formed integrally with the collar (2) with a thin web separating the two to define a fracture line. The lid (31) is provided with a grip (34) which can be grasped from within the process area. Application of a pulling force to the grip (34) causes the lid (31) to be pealed away from the collar (2) without the generation of particulates.



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TEAR–OPEN SPOUT FOR A CONTAINER

The present invention relates to a closure for a container used in the transfer of materials or components between a contained isolation or clean-room process area and a non-sterile outside environment.

Transfers of sterilised materials between sterile or clean areas via the outside environment are routinely made in industries such as the pharmaceuticals, medical devices, biotechnology and food industries. Typically, a container or bag, the interior of which is sterile, is offered up to and coupled with a port in a wall of the process area. After conducting a sterilising cycle to sterilise the interface between the container and the port, a door in the port is opened to permit an operator located within the process area to gain access to the container and to remove a cap or lid from the container, thereby enabling the sterile interior of the container to be charged with sterile materials, or to permit sterile materials to be unloaded from the container into the process area.

Typically, the cap or lid of the container comprises a flexible foil which is sealed over the mouth of an opening provided in the container. The operator may remove the foil manually by punching it to rupture the foil, then pushing the broken foil pieces toward the rim or mouth to provide free access to the container interior via the mouth. Alternatively, the operator may use a sharp instrument to cut through the foil. Both methods are likely to generate some non-viable particulate material, which may enter the process area, contrary to good manufacturing practice codes in these industries. Both methods are also susceptible to causing perforation to be made in the operator's gloves, which could introduce viable particulate into the system, compromising the cleanliness of the process area. To avoid these problems, the foil may be provided with a tab which can be grasped by the operator to assist him in peeling the foil, in an unbroken state, from the container mouth. In such cases, care must be taken to ensure that whichever sterilising means is used to sterilise the interface between the coupled container and dock is effective to sterilise all surfaces of the tab.

An effective coupling assembly for a container and a port is disclosed in WO96/21615 and comprises a collar of substantially tubular shape which docks with the port of a process area. The collar forms part of a transportable container. The port includes a door which opens inwardly into the process area. To the exterior facing side of the door are mounted ultraviolet (UV) or pulsed white light emitting sources which emit radiation at a frequency effective for sterilisation. On docking of the collar and port, a sealed chamber is established between the port and the collar and this chamber is sterilised by activation of the UV or pulsed white light lamps for a sufficient amount of time. Thereafter, the port door is opened and a foil covering the mouth of the collar can be removed to enable materials or components to be transferred between the container and process area. It will be appreciated that the foil will have a pull tab to facilitate its removal and that it is a matter of some difficulty to arrange the tab in such a way as to ensure that none of its surfaces are shadowed from the sterilising radiation. Such shadowing may occur as illustrated in prior art Figure A, which shows a peel-off foil F covering the mouth M of the collar C of a container (not shown). The foil F is sealed to the mouth M by glue G. The foil F overlaps the mouth M at O, the overlap providing a grippable area which an operator can grasp to remove the foil F. However, it will be appreciated that while the upper surface F' of the foil lies in the direct line of the sterilising radiation (shown by the arrows), the underside surface F'' of the overlapped portion is shadowed from the sterilising radiation by the foil F itself and this area constitutes a potential source of viable contamination of the entire process area once the foil has been peeled away.

The present invention seeks to overcome the above described disadvantages of heretofore used foils or seals and to provide an improved seal in which the risk of contamination is minimised. In particular, a seal which is especially suitable for use with the assembly described is WO 96/21615, is provided.

Accordingly the present invention provides a closure for a transportable container usable in the transfer of materials to or from a sterile or clean process area via a non-sterile environment, the closure being dockable with a port located in a wall of the process area

to form a sealed connecting chamber, the closure comprising a collar portion arranged to lock with the port and a lid portion which is removably connected to the collar portion, the arrangement being such that following locking of the closure with the port and sterilisation of the sealed connecting chamber, the lid portion is removable from within the process area to provide communication between the interiors of the container and the process area, the collar and lid portions being so formed and shaped that i) all surfaces thereof which form part of the sealed connecting chamber lie in use in the direct path of sterilising ultra-violet or pulsed white light radiation generated within the chamber with no surface or portion of a surface being shadowed from the radiation and ii) the lid portion is removable without the generation of particulate material. The lid portion may include a grip member grippable to assist in the removal of the lid portion from the collar portion. The lid portion may be bonded to or integrally formed with the collar portion and may be fabricated from plastics material by injection moulding or other suitable means.

In a preferred arrangement, the junction between the lid and collar portions comprises a thin, frangible web or material defining a fracture line between the two portions and the grip member is disposed so that when it is pulled in a direction away from the collar portion, the web is caused to break along the fracture line to release the lid portion from the collar portion.

The collar portion may be formed with an exterior surface which tapers towards the junction with the lid portion and the tapering surface may continue over and beyond the junction by the provision of a matching taper on the outer surface of the rim of the lid portion. Conveniently, the lid portion has a planar surface which covers the mouth of the collar and which faces the port in use, and the grip member is associated with the planar surface. In a preferred arrangement, the grip member is disposed about at least a portion of the rim of the lid portion. Most conveniently, the grip member is substantially triangular in cross-section, one side of the triangle comprising a tapered outer surface of the lid rim.

The collar is conveniently provided with a flange which is sealingly connectable to a surface of the container and the flange extends radially outwardly from the collar portion. Most conveniently, the flange is formed integrally with the collar portion. In a preferred arrangement, the flange has a planar surface which is sealingly connectable to a planar surface of the container. The surface of the flange which is connected to the container may be flat or sloped. The attachment of the surfaces of the container and collar may be made by any suitable means capable of providing a strong seal between the two, for example, by adhesive or by welding.

The closure may include a sensor means connectable with a sensory device provided in the port.

The invention also provides a transportable container having a closure as described above.

One embodiment of a seal according to the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a partially sectional side view of a closure for a transportable container according to the invention;

Figure 2 is a view from below of the closure of Figure 1;

Figure 3 is a view identical to Figure 1, showing one set of suitable dimensions for the parts;

Figure 4 is a detail view of the collar/lid junction of Figure 1;

Figure 5 is a view showing the docking of the closure of Figure 1 with a port of a process area;

Figure 6 is a detail view of a section of Figure 5, showing more clearly the position of the collar;

Figure 7 is a partially sectional view of the closure of Figure 1, showing a gripping tool for removing the lid;

Figure 8 is a partially sectional side view of a cap for the closure;

Figure 9 is a partially sectional side view of the closure assembled with the cap; and

Figure 10 is a view of a modified form of the closure of Figure 1.

Referring initially to Figures 1 to 4, the closure 1 comprises a collar 2 and a seal 3. At the base of the collar 2 is provided a circumferentially and radically outwardly extending flange 4, under or over which a container (not shown) can be sealingly fixed. The container may be flexible or otherwise. The container, collar and seal comprise together a sterilisable transportable system usable for transporting sterile materials through an unsterile environment to or from a sterile or clean process area. Intermediate the flange 4 and seal 3, the collar 2 is provided on its exterior facing surface with a circumferentially extending projection 5, which serves to help prevent the disengagement of the closure 1 from a port of a process area after docking has been established, as will be described below with reference to Figures 5 and 6.

One embodiment of the seal 3 and its junction with the collar 2 will now be described with particular reference to Figure 4. Seal 3 comprises a lid 31 having a flat surface 32 which faces the port during docking. The rim 33 of the lid 31 is formed integrally and continually with the upper wall portion 21 of the collar 2. The junction 36 between wall 21 and lid 31 is formed, on its outwardly facing side, as a frustoconical surface 10 tapering towards the apex 35 of a grippable ridge 34 of the lid 31. Ridge 34 is formed

about the circumference of the lid surface 32 and stands proud of the rim 33. The surface 11 of the inside wall of ridge 34 tapers from surface 32 toward the apex 35.

Due to the frustoconical taper of surface 10, part of which is provided by a tapering reduction in thickness of the upper portion of collar wall 21 and the remainder of which is provided by a tapering reduction in thickness of rim 33, a relatively thin-walled junction 36 is formed between collar 2 and lid 31. This junction 36 represents a point of weakness or a fracture line (36) which can be exploited to enable the lid 31 to be torn from the collar 2. This is achieved by applying a double jawed gripping tool (Figure 7) to the ridge 34 so as to engage one jaw of the tool against the outwardly facing sloping surface 10 of the ridge 34 and the second jaw against the inwardly facing sloping surface 11 of the ridge 34. To facilitate gripping, the jaws are preferably toothed. Then, by applying a force to the tool in the direction of the arrow A (Figure 4), the thin wall at junction 36 is ruptured by the jaws. The lid 31 may then be removed intact by peeling it away from the collar 2, rupturing along the fracture line formed by the thin wall.

As shown in Figure 3, one suitable arrangement of the ridge 34 is where the angle between the frustoconical surface 10 and the surface 32 is 45°. Other suitable dimensions for one arrangement of the collar are also shown in the Figure and it is to be understood that these dimensions are exemplary in nature and not to be in any way considered as limiting.

Figures 5 and 6 demonstrate the docking of the assembly 1 with a port such as that described in WO96/21615. Port 50 is fully described in that document and accordingly will now be described only insofar as necessary to convey a full appreciation of the invention disclosed herein. Accordingly, port 50 includes a door 51, shown closed in Figures 5 and 6. On the outwardly facing side 51a of the door are mounted seven UV lamps 52. Sleeve 53 of the port 50 is adapted to receive the collar 2 and to lock it into position coupled with the port shown in Figures 5 and 6.

A locking mechanism, generally indicated by numeral 54 is actuable to engage the external surface of the collar wall 2 between projection 5 and flange 4, to retain the collar 2 in place and to prevent it from accidentally disengaging from the port 50 during a transfer. As the projection 5 extends around the entire outer circumference of the collar 2, it will be appreciated that there is no need to offer up the collar 2 to the port 50 in any particular rotation about the longitudinal axis x of the collar (Figure 1) and this feature allows for easy and speedy establishment of docking between the collar 2 and port 50.

Once docking of the collar 2 with sleeve 53 has been achieved and verified by the display of a "ready" message on a connected programmable logic controller, various seals are actuated to bear between the exterior of the collar 2 and the interior of the port 50. thus forming a sealed connection chamber 55 between the mouth area of the collar 2, the exterior of the lid 31 and the door 51 of the port 50. First. the secondary environmental seal 250 is inflated. sealing the transfer interface. The pressure in the secondary seal is verified as correct according to specification and constant. Next, the UV lamps 52 are activated to sterilise the vertical contact surface between the primary environmental seal 251 and the horizontal interface surface of collar 2, including lid 31. After a predetermined time and with the UV lamps 52 remaining activated, the primary environmental seal 251 is inflated. Irradiation is continued for a predetermined period of time sufficient to sterilise the volume enclosed by the chamber 55, together with the exposed surfaces of the port 50, collar 2, primary environmental seal 251 and lid 31, to achieve a reduction of contaminants by at least a factor of 10^{-6}. After the sterilisation cycle is complete, door 51 may be safely opened inwardly into the process areas. It will be appreciated that all surfaces which form part of the chamber 55 are directly exposed in the path of the UV radiation generated by lamps 52 and no potentially contaminated surfaces of the sleeve 53, door 51, collar 2 or lid 31 which become continuous with the process area on opening of the door 51 are shadowed from the sterilising radiation. The tapering surfaces 10, 11 and the lid surface 32 are so formed that all parts of the collar 2 receive the sterilising radiation impacting directly on them. Although not shown so in the figures, the collar 2 may be formed so that its exterior facing wall tapers toward the

upper wall portion 21, for example by a 2° slope. The slope in the wall of the collar would further facilitate the sterilisation of the surface of the exterior wall of collar 2.

Once door 51 is opened, an operator working within the process area may reach through with the gripping tool as shown in Figure 7 and use it to grasp the ridge 34 anywhere about its circumferential length. Next, by pulling on the tool, the operator is enabled to break the lid 31 from the collar as described above, to remove it completely from the collar and to withdraw it into the process area. The lid 31 thus may be cleanly removed without the generation of particulates. Free access between the interior of the container C sealed to the flange 4 of the collar is thereafter available.

A gripping tool suitable for removing the lid 31 is shown in Figure 7. The tool 800 has a pair of legs 801, 802 each of which has a handle 803. Distal each handle 803 is a jaw, leg 801 having jaw 804 and leg 802 having jaw 805. The legs 801, 802 are pivoted together for relative movement. In use, jaw 805 bears against the inwardly sloping surface 11 of the ridge 34 and jaw 804 bears against the outwardly sloping surface of the ridge 34. When the jaws 804, 805 are pivoted toward one another, the force applied to the ridge 34 serves to break it at its weakest point, that is to say, at junction 36. Once the break has been made, the lid 31 may be peeled off with the jaws gripping the ridge.

The tool 800 may be operated manually or may be arranged for automatic operation. In the latter case, the tool 800 may be connected to the port of the clean, process enclosure area.

Regarding the attachment of the closure 1 to a container, this may advantageously be achieved by flat welding a planar surface of the container to a planar surface of the flange 4. This may be done automatically using a welding tool which has an unbroken welding surface shaped to match that of the face of the flange 4 to which the container is to be attached, resulting in a high quality, secure weld being formed. Such a weld enables checking for leaks between the container and the closure to be done by spot-checking

randomly selected containers, rather than, as before, checking each individual container for leaks.

Formerly, it has been the practice to bring the container and closure together manually in preparation for welding these parts together. Generally, the container is a flexible bag with a mouth wider than the width of the closure. Thus, once the closure is inserted into the mouth, the material of the bag is gathered manually about the closure. The presence of the gathers makes it difficult to carry out the welding step using a single tool and a single weld, so that the weld must be made manually in a series of welding steps. The manual operation can vary from container to container and consequently verification of the weld and of the integrity of the resulting container can not be done on the basis of testing randomly selected containers. In consequence, each container must be checked for leaks at the interface between container material and the container closure and this places a high cost burden on the manufacture of such bags. Furthermore, the significant manual intervention required poses an unacceptably high risk of introduction of both viable and non-viable particulate contaminants.

By welding the closure to an orificed planar surface of the container, as described herein, the container manufacture in its totality can be performed under class 100 clean conditions. Both the manufacture of the container itself and the attachment of the container closure can be carried out automatically in-line. Operator intervention is minimal and hence, the introduction of viable and non-viable particulates is minimised and the costs associated with manual assembly are reduced. Additionally, significant savings are obtained by eliminating the need to check each final container for leaks.

Figure 8 shows a modification of the collar 2 in which flange 41 is formed with sloped walls. The sloped walls of the flange 41 are suitable to receive the container connected thereto by a welding or other bonding process.

In the collar described above, it will be appreciated that the lid 31 is integrally formed with the walls of the collar and that no tab or other structure is present which could, in

use when docked, be shadowed from the sterilising radiation. Instead, the construction is such that all surfaces which become part of the process area on completion of the docking cycle are in the direct path of the sterilising radiation. Furthermore, the lid covering the collar can easily be removed without generation of particulates.

The closure of the invention may equally be used in docking systems which use sterilising means in addition to or other than UV or pulsed white light, for example, in systems which use steam or sterilising gases to sterilise the coupled port and container interface.

The lid and collar may be formed integrally, for example by injection or other moulding with suitable plastics materials. Equally, they may be bonded together with a suitably formed area of weakness to define the fracture line which can be easily breakable to enable separation of lid from collar. or may be formed in any other suitable way. Likewise, the lid may be formed wholly separately from the collar and be adapted to fit with the collar in some suitable way, such as by an interference or a screw fit. The arrangements in which the lid and collar are connected by being formed together, such as by bonding or by being integrally formed. are preferred. since containers using this preferred arrangement can readily be inspected to ensure that the connection between the lid and collar is unbroken and hence the sterile status of the interior of the container has not been intentionally or unintentionally compromised.

The grip or ridge of the lid may be formed with any other suitable profile other than the triangular cross-section shown in the drawings. For example, it may have a rounded or humped shape. It may also be formed about only a part of the rim of the lid, or may be positioned not on the circumference of the lid. but elsewhere on its surface, for example as a central stud.

Most advantageous is to provide the grip in such fashion that it is easily accessible from within the process area and that it may be used as easily by a left-handed as a right-handed operator. For this reason, it is particularly preferred that the grip be provided as a

ridge extending about the entire rim of the lid, as this obviates any need to locate the collar in any particular rotation within the dock and accounts for its easy accessibility for left- and right-handed persons. It is important that when it is to be used with UV or pulsed white light sterilisation, all the external surfaces of the collar and lid which become part of the sealed connecting chamber on docking of collar and port, are shaped to lie in the path of the sterilising radiation and that none of these areas are shadowed from the sterilising radiation so as to constitute actual or potential sources of contamination of the process area.

The lid and collar portions need not be formed with a generally circular cross-sectional shape. Any other suitable shape, including square, rectangular, triangular, oval etc., may be selected. The circular shape is a particularly preferred arrangement since it avoids the need for the collar to be offered up to the port in any particular axial rotation.

Generally, the transportable container will be manufactured with the intact closure arranged about a discharge opening of the container, and a further opening provided elsewhere in the container to enable the container to be charged with materials or components. Once charged, the further opening will be sealed and the container subjected to sterilisation. Only when the contents are to be withdrawn therefore, need the closure be interfered with to remove the lid and to enable the contents to be accessed from the interior of the process area.

The container may have one or more closures formed in it. One closure may be employed for aseptically charging a pre-sterilised container, then that closure would be sealed. A second closure may be provided to enable a portion of the contents of the bag to be discharged and third and further closures could be provided to allow remaining contents or portions thereof to be discharged at a later time or times.

In cases where the seal/lid is formed separately from the collar and engages with the collar by an interference, screw or other form of fit, then it will normally be desirable to provide a means of demonstrating to the end-user that no tampering has occurred to

compromise the sterility of the interior of the container. This may be achieved by the use of an anti-tamper closure such as those commonly used in the art or by the simple use of a heat or radiation sensitive tape placed about and over the junction between the lid and collar. Since the interference fit lid can readily be removed and replaced, it offers the advantage that only a single opening need by provided in the container, the same opening being usable for charging, discharging and indeed, if desired, recharging the container. Thus, in appropriate cases, it will be appreciated that the container may readily be recycled.

As shown in Figures 8 and 9, the collar is advantageously provided with a sealable cap 60 to protect the closure from mechanical damage, dust, dirt and so on during transit and storage. The cap 60 would also serve to limit the biological burden on the collar parts which become exposed during a transfer and for this purpose, the cap 60 is designed to cover and protect those parts of the collar and lid which form part of the sterile connection chamber on docking of the container with the port of the sterile or clean room. In a preferred arrangement, the cap 60 is disposed to rest against the circumferentially extending projection 5, thus ensuring that the travel of the cap 60 over the closure 1 is limited and that the cap may not be pressed sufficiently over the collar so as to risk damaging the lid 31. The cap may be sealed to the collar with tape (not shown) or may be pressed over the collar as a snap-fit or both. The sealing tape may be of a heat or radiation sensitive type, depending on the sterilising method employed to sterilise the container so that an operator can tell at a glance that the sealed container has undergone a sterilisation cycle. Clearly, those parts of the apparatus under the cap will be sterilised during the sterilisation cycle. Additionally, the cap may be provided with a panel of a material which is porous to gas, such as sterilising steam, but impervious to biological contaminants and which would therefore allow gas generated during sterilisation to be vented from the interior of the container. One suitable material for this purpose is Tyvec (Trade Mark).

It is further to be understood that the collar may be provided with a sensor co-operable with sensing means which may be provided in the port of the process area. Such a sensor

could provide a number of functions, including but not limited to enabling the operator to ensure that the collar is correctly engaged in the port and the accumulation of tracking records, for example by enabling a record of which individually coded containers and which number of containers have been processed via a particular port to be kept.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention as defined in the appended claims.

Claims:

1. A closure for a transportable container usable in the transfer of materials to or from a sterile or clean process area via a non-sterile environment, the closure being dockable with a port located in a wall of the process area to form a sealed connecting chamber, the closure comprising a collar portion arranged to lock with the port and a lid portion which is removably connected to the collar portion, the arrangement being such that following locking of the closure with the port and sterilisation of the sealed connecting chamber, the lid portion is removable from within the process area to provide communication between the interiors of the container and the process area, the collar and lid portions being so formed and shaped that i) all surfaces thereof which form part of the sealed connecting chamber lie in use in the direct path of sterilising ultra-violet or pulsed white light radiation generated within the chamber with no surface or portion of a surface being shadowed from the radiation and ii) the lid portion is removable without the generation of particulate material.

2. A closure according to claim 1, in which the lid portion includes a grip member grippable to assist in the removal of the lid portion from the collar portion.

3. A closure according to claim 2, in which the lid portion is bonded to or integrally formed with the collar portion.

4. A closure according to claim 2 or 3, in which the junction between the lid and collar portions comprises a thin, frangible web or material defining a fracture line between the two portions and the grip member is disposed so that when it is pulled in a direction away from the collar portion, the web is caused to break along the fracture line to release the lid portion from the collar portion.

5. A closure according to any preceding claim which is fabricated from a plastics material.

6. A closure according to any preceding claim in which the collar portion is formed with an exterior surface which tapers towards the junction with the lid portion.

7. A closure according to claim 6, in which the tapering surface continues over and beyond the junction by the provision of a matching taper on the outer surface of the rim of the lid portion.

8. A closure according to any preceding claim in which the lid portion has a planar surface which covers the mouth of the collar and which faces the port in use.

9. A closure according to claim 8, in which the grip member is associated with the planar surface.

10. A closure according to any of claims 2 to 9, in which the grip member is disposed about at least a portion of the rim of the lid portion.

11. A closure according to any of claims 2 to 10, in which the grip member is substantially triangular in cross-section, one side of the triangle comprising a tapered outer surface of the lid rim.

12. A closure according to any preceding claim in which the collar is provided with a flange which is sealingly connectable to a surface of the container.

13. A closure according to claim 12, in which the flange extends radially outwardly from the collar portion.

14. A closure according to claim 13, in which the flange is formed integrally with the collar portion.

15. A closure according to any of claims 12 to 14, in which the flange has a planar surface which is sealingly connectable to a planar surface of the container.

16. A closure according to any of claims 12 to 15, in which the container and flange are welded together.

17. A closure according to any preceding claim including a sensor means connectable with a sensory device provided in the port.

18. A transportable container having a closure according to any of the preceding claims.

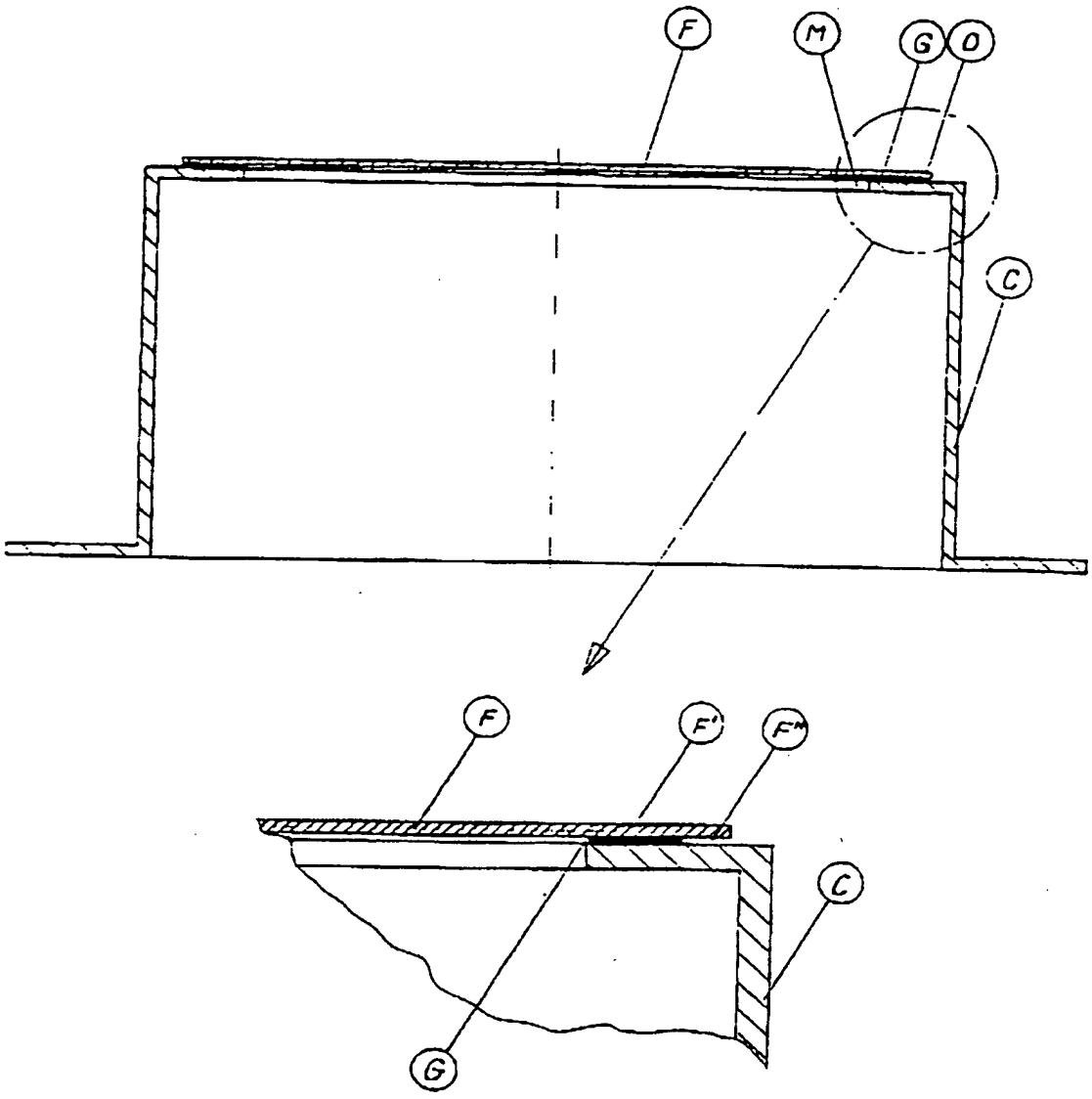

FIGURE A (PRIOR ART)

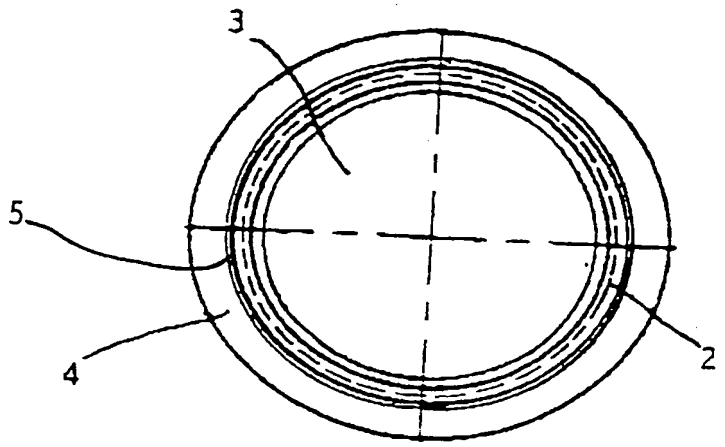

FIGURE 2

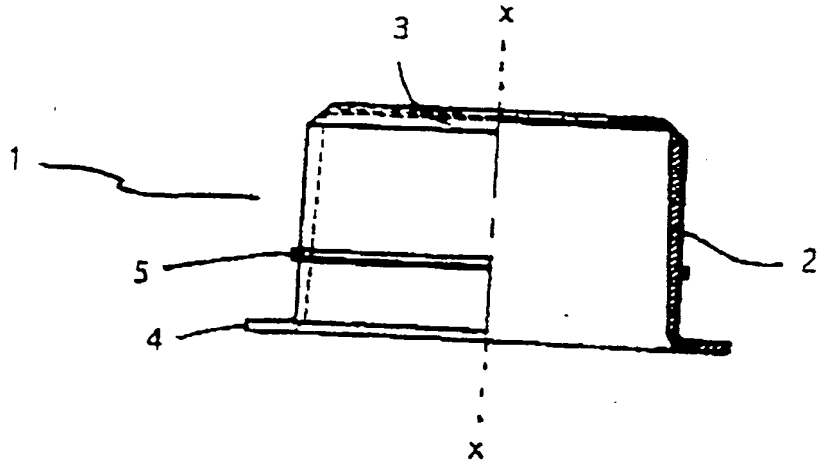

FIGURE 1

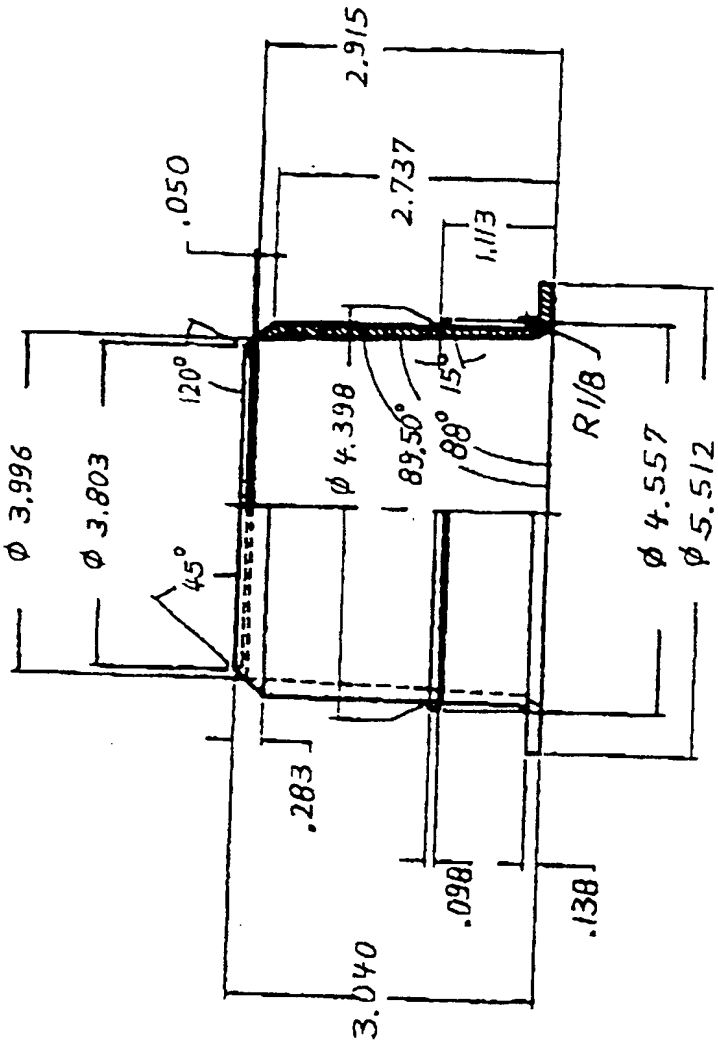

FIGURE 3

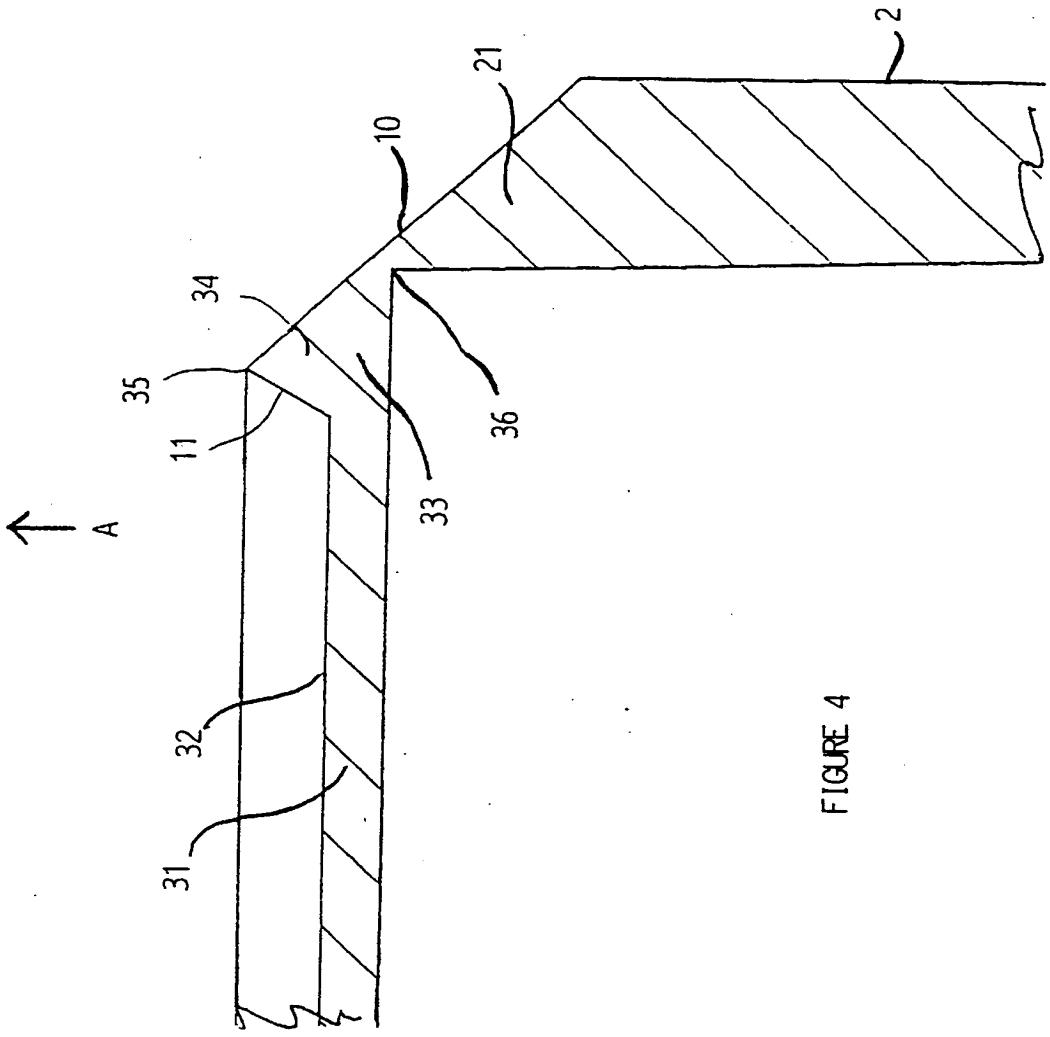

FIGURE 4

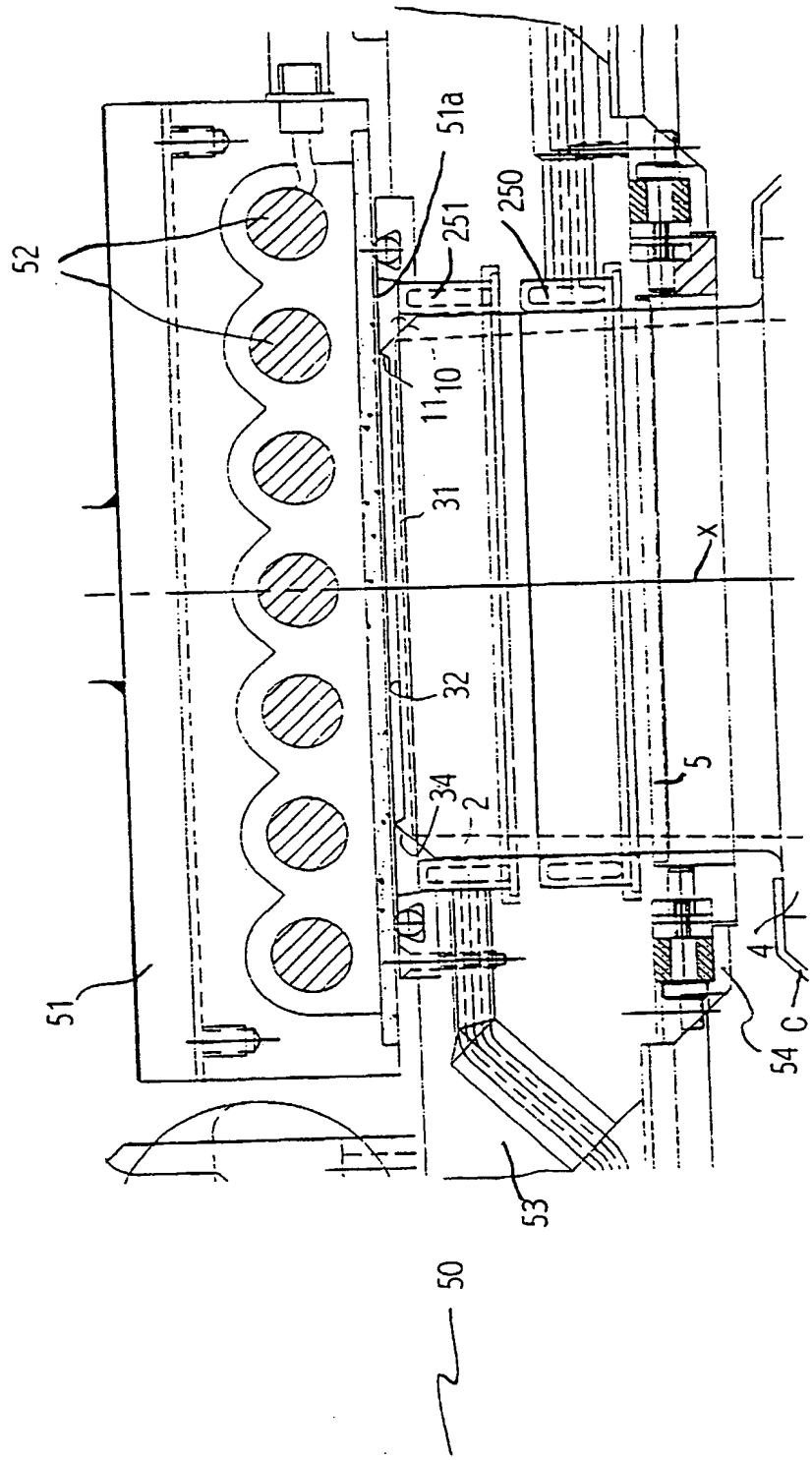

FIGURE 5

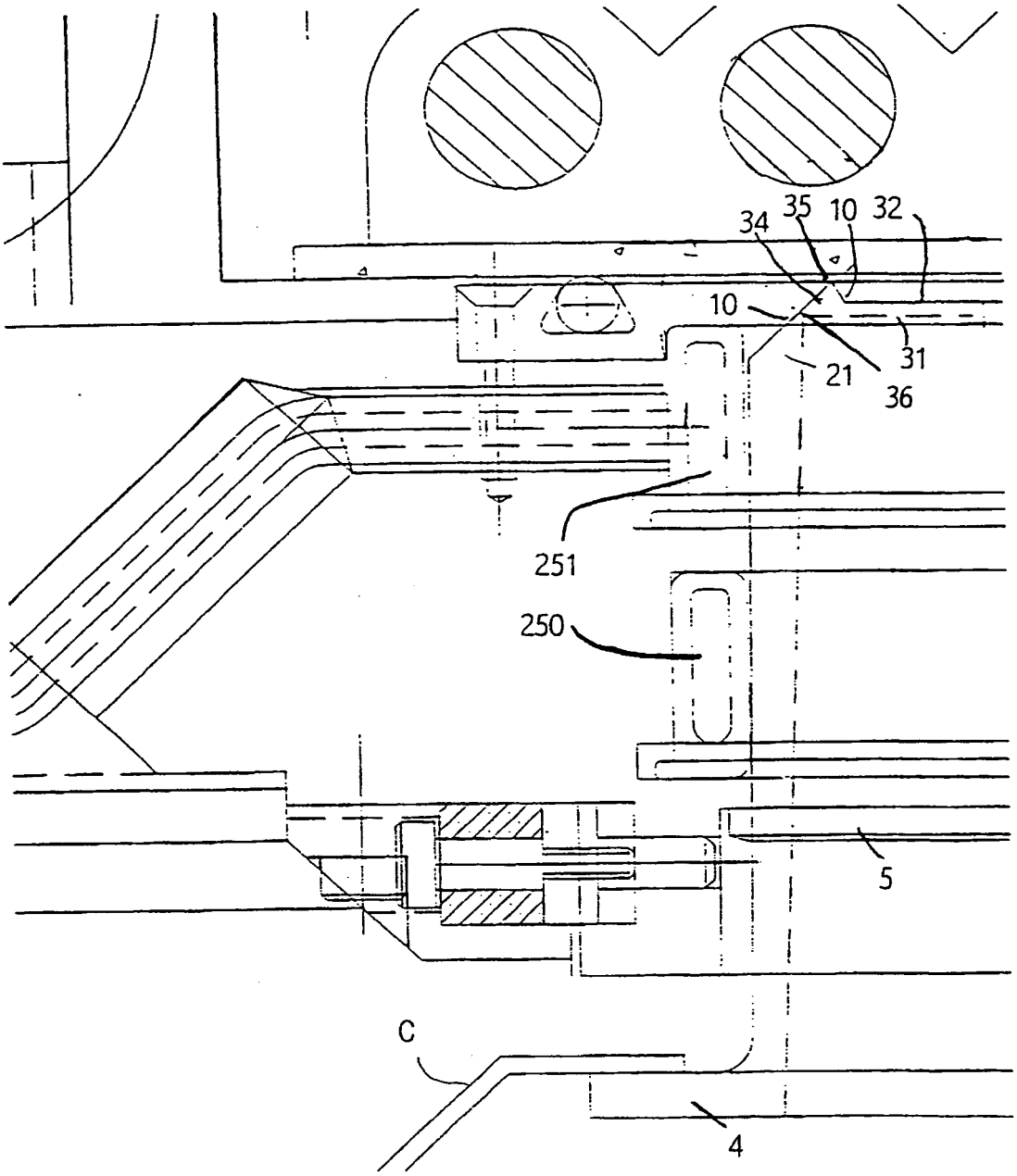

FIGURE 6

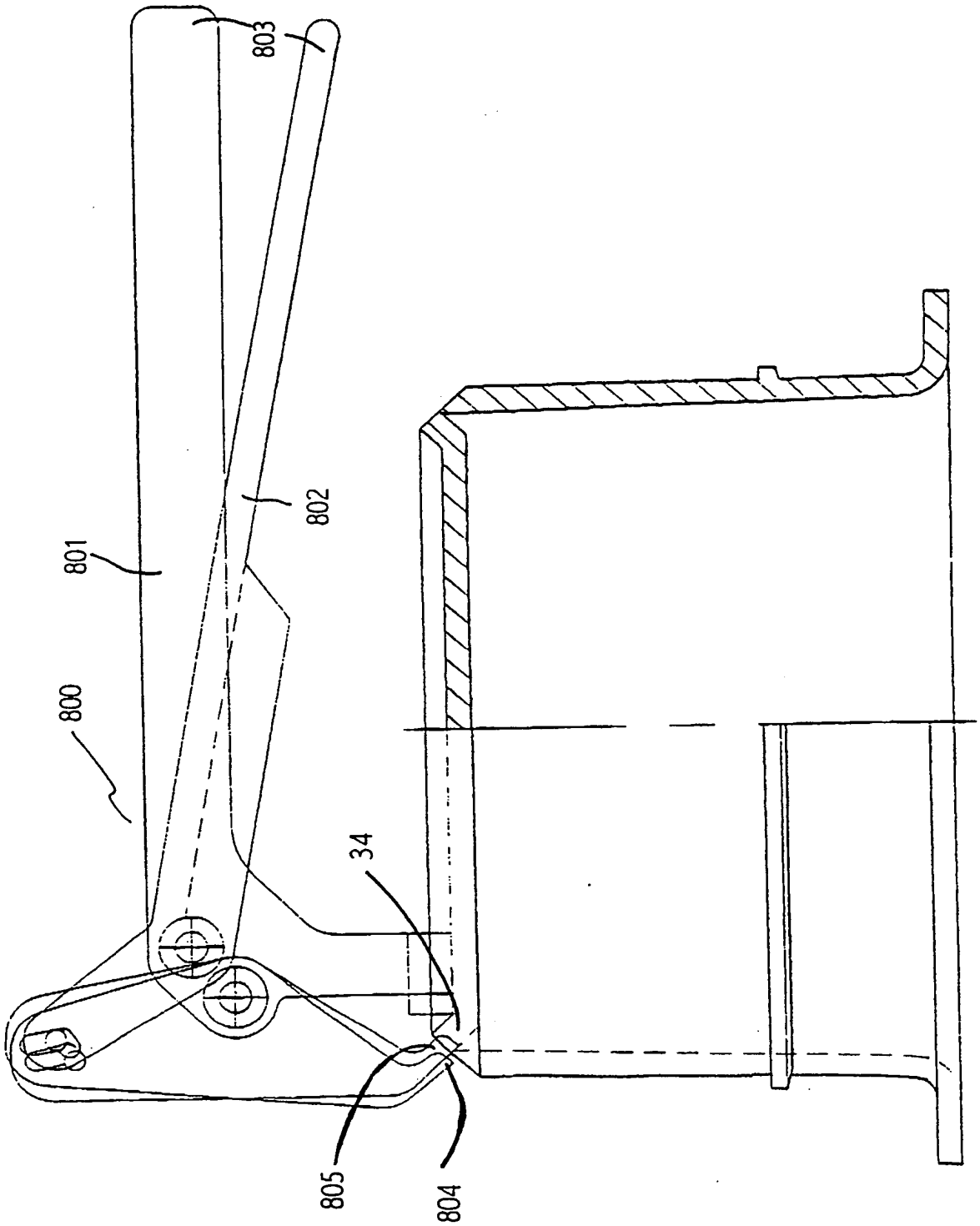

FIGURE 7

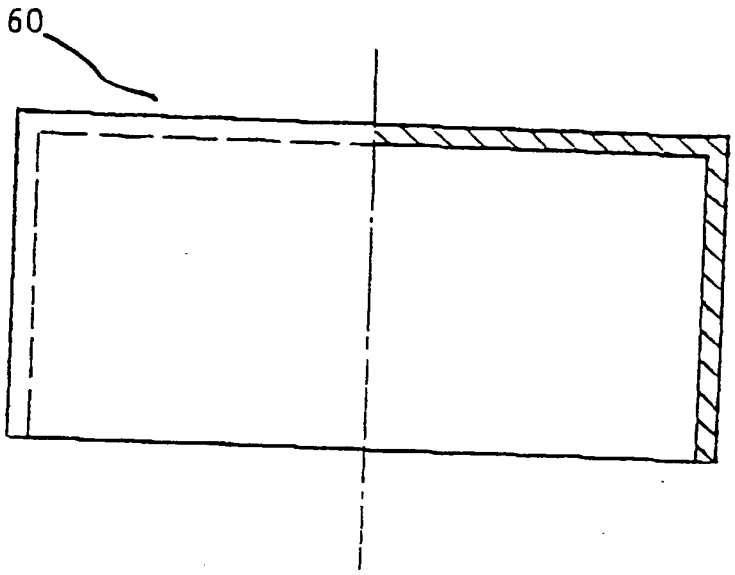

FIGURE 8

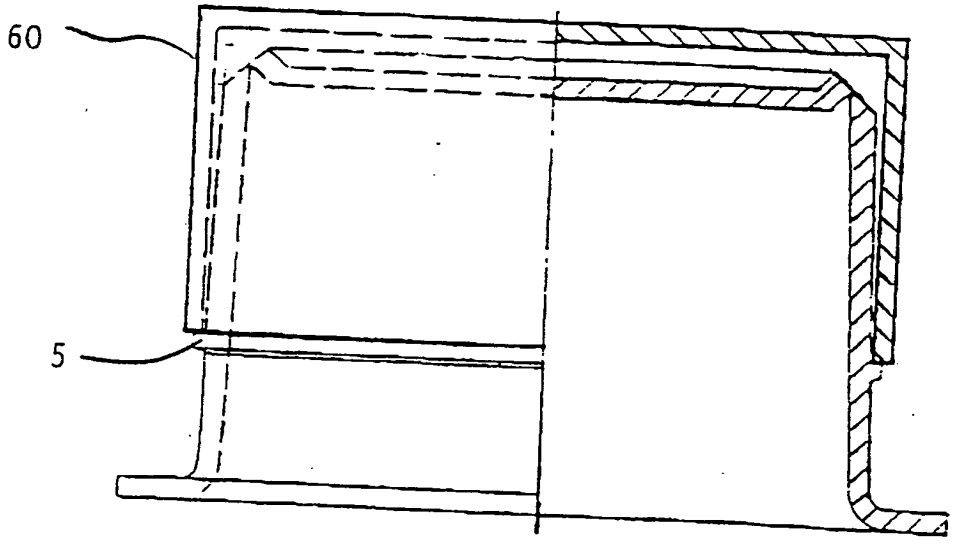

FIGURE 9

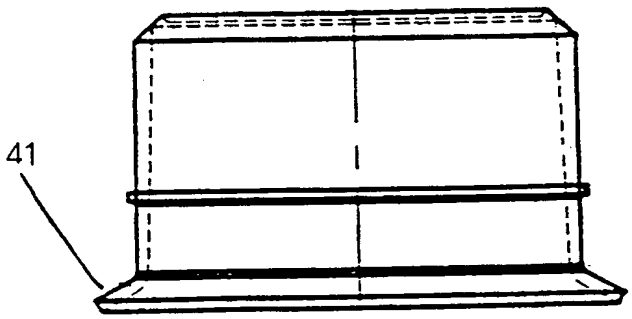

FIGURE 10

INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/IE 98/00006

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D47/36 B65D75/58

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D B67D

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 21615 A (DURAS) 18 July 1996 cited in the application see the whole document	1-6, 8-10, 12-18
A	WO 89 07575 A (NOW TECHNOLOGIES) 24 August 1989 see page 5, line 25 - page 16, line 22; figures 1-12	1
A	US 4 903 855 A (DUCAY) 27 February 1990 see column 3, line 18 - line 30 see column 5, line 24 - line 36; figures 6,7	2-7,9,11
A	GB 688 534 A (RIEKE) 11 March 1953 see figures 8-10	2

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
25 May 1998	04/06/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Newell P

1

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication.where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 355 729 A (MAGUIRE) 26 October 1982 see figures 1,4,5	2
A	BE 546 400 A (BELMOPLAST) 14 April 1956 see page 4, line 33 - page 5, line 14; figure 2	7,11

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .onal Application No
PCT/IE 98/00006

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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International Bureau

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(71) Applicant: THE WEST COMPANY, INCORPORATED [US/US]; 101 Gordon Drive, Lionville, PA 19341 (US).

(72) Inventor: NORTON, Paul, H.; P.O. Box 3, Trumbauersville, PA 18970 (US).

(74) Agents: HUIS, Randolph, J. et al.; Panitch Schwarze Jacobs & Nadel, P.C., 36th floor, 1601 Market Street, Philadelphia, PA 19103 (US).

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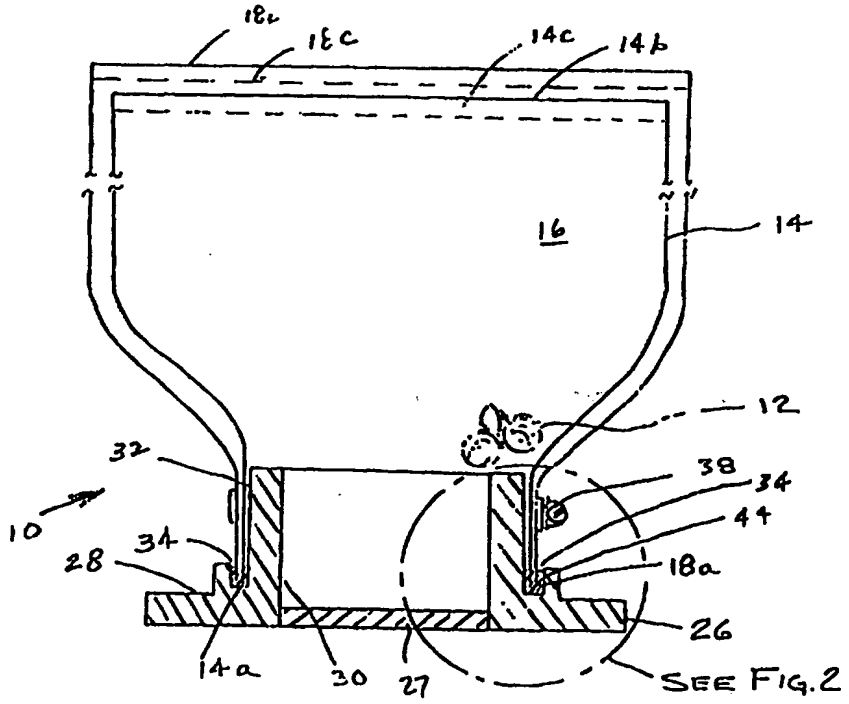
Published
With international search report.

(54) Title: CONTAINER FOR HOLDING STERILIZED ELEMENTS

(57) Abstract

A container (10) for holding elements (12) to be sterilized prior to introduction into an isolation system. The container includes a flexible bag (14) having a first end (14a) defining a first opening for removing the elements. The bag includes a transfer port (26) that is engageable with the isolation system for transferring the sterilized elements into the isolation system. The transfer port has a bore (30) extending through it. The exterior surface (28) of the bore has a clamp receiving area (32) and a groove (34). The first end of the bag is located in the groove. A clamp (38) is located around the flexible bag near the first end. A portion of the flexible bag is clamped between the clamp and the clamp receiving area on the transfer port. A sealing material (44) is located in the groove and encapsulates the first end of the flexible bag to form a hermetical seal.



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CONTAINER FOR HOLDING STERILIZED ELEMENTS

Field of the Invention

The present invention relates to a container for holding sterilized elements and, more particularly, to a container having a transfer port for transferring the sterilized elements into an isolation system or other sterile area.

Background of the Invention

In the past, packaging of sterile products was carried out in clean rooms which were maintained in an isolated, sterile environment. Personnel working in such clean rooms generally had to be entirely covered in protective clothing to prevent contamination of the equipment or products being packaged.

In order to avoid the expense of operating and maintaining clean room environments, barrier-isolated equipment has been introduced which maintains a local sterile environment directly around the equipment which can be accessed through glove portals or by other means. This eliminates the requirement for a clean room and results in

savings in capital costs, as well as reduction of losses due to contamination.

There is a requirement for introducing parts or other material into such isolated systems without jeopardizing the sterility of the parts or the atmosphere within the isolated system. One method for solving this problem involves providing a cleaning and sterilizing machine next to the isolation system. The machine includes a treatment vessel which receives the articles to be sterilized, such as closure elements for pharmaceutical containers. The closure elements are sterilized within the treatment vessel and are then passed into the isolation system. Prior to passing the closure elements from the treatment vessel to the isolation system, the conduit between the treatment vessel and the isolation system is sterilized.

However, positioning a cleaning and sterilizing machine proximate to an isolation system, as described above, requires the processing and packaging company to incur additional cost for the cleaning and sterilizing machine, as well as requiring additional room for the cleaning and sterilizing equipment adjacent to each isolation system.

Another solution to this problem, which is described in U.S. Patent 5,447,699, which was jointly invented by the present inventor and is assigned to the assignee of the present invention, provides a combination

container for holding sterilized elements, such as vial stoppers, and a sterilizable transfer port for transferring the sterilized elements located on the isolation system. The container is formed of a flexible bag which receives the sterilized elements and a collar having a sealed closure which can be sterilized when it is connected to the isolation system to transfer the elements from the container to the isolation system. This allows the required sterilized elements to be sterilized at a different location prior to shipping to the processing and packaging company where the sterilized elements are fed in to the isolation system, such as a system for bottling pharmaceuticals.

One problem with the known containers for holding and storing sterilized elements is the connection between the collar or transfer port component of the container for holding the sterilized elements and the flexible bag component. In order to assure that the sterilized elements within the bag remain in their sterile condition, the connection between the flexible bag and the rigid transfer port or collar must be hermetically sealed to prevent ingress of bacteria, moisture or other contaminants. If the seal between the flexible bag component and the transfer port component is not hermetically sealed, then the entire container of sterilized elements cannot be used and must either be scrapped or shipped back to the provider for reprocessing and sterilizing.

Summary of the Invention

Briefly stated, the present invention comprises a container for holding elements to be sterilized prior to introduction into an isolation system having an isolated inner region. The container includes a first flexible bag defining a cavity for containing the elements. The flexible bag includes a first end defining a first opening for removing the elements from the flexible bag. A transfer port is attached to the first end of the flexible bag. The transfer port is engageable with the isolation system for transferring the sterilized elements into the isolation system. The transfer port has an exterior surface which includes a clamp receiving area, and a bore extends through the transfer port and exterior surface. A groove is located in proximity to a first end of the bore. The first end of the first flexible bag is located in the groove. A clamp is located around the flexible bag proximate to the first end. A portion of the flexible bag is located between the clamp and the clamp receiving area on the transfer port to clamp the flexible bag to the transfer port. A sealing material is located in the groove and encapsulates the first end of the first flexible bag to hermetically seal the first flexible bag to the transfer port.

In another embodiment, the present invention provides a method of producing a containing for holding sterilized elements, with the container including a transfer

port for connection to an isolation system. The method comprises the steps of:

providing a flexible bag having a first end defining a first opening;

encapsulating the first end of the flexible bag in a groove in a transfer port which is engageable with the isolation systems;

clamping a portion of the flexible bag proximate to the first end of the flexible bag to the transfer port.

Brief Description of the Drawing

The foregoing summary, as well as the following detailed description of preferred embodiments of the invention, will be better understood when read in conjunction with the appended drawing. For the purpose of illustrating the invention, there is shown in the drawing embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown. In the drawing:

Fig. 1 is a cross-sectional view of a container in accordance with the present invention;

Fig. 2 is an enlarged fragmentary view of a portion of Fig. 1; and

Fig. 3 is an enlarged fragmentary view of a second embodiment of the invention similar to Fig. 2.

Detailed Description of Preferred Embodiments

Certain terminology is used in the following description for convenience only and is not limiting. The words "right," "left," "lower" and "upper" designate directions in the drawings to which reference is made. The words "inwardly" and "outwardly" refer to directions toward and away from, respectively, the geometric center of the container for holding sterilized elements and designated parts thereof. The terminology includes the words above specifically mentioned, derivatives thereof and words of similar import.

Referring to the drawing, wherein like numerals indicate like elements throughout, there is shown in Figs. 1 and 2 a first preferred embodiment of a container 10 for holding elements 12 (only a representative sample being shown), which are to be sterilized prior to introduction into an isolation system (not shown) having an isolated inner region. Isolation systems are well known to those of ordinary skill in the art, and therefore, further description is omitted for purposes of convenience only, and is not considered limiting. One system which utilizes a container comprising a flexible bag affixed to a collar or transfer port which can be connected to a port on an isolation system is described in U.S. Patent 5,447,699, which is incorporated herein by reference as if fully set forth.

Referring now to Figs. 1 and 2, the container 10 of the present invention comprises a flexible bag 14 which defines a cavity 16 for containing the elements 12. The flexible bag 14 includes a first end 14a which defines a first opening for removing the sterilized elements from the first flexible bag 14, and a second end 14b which defines a second opening for placing the elements 12 to be sterilized in the first flexible bag 14.

In the first preferred embodiment, there are two flexible bags 14, 18. The first flexible bag 14 is located inside the second flexible bag 18, and each flexible bag 14, 18 has first and second ends 14a, 18a, 14b, 18b, respectively, with the first ends 14a, 18a defining first openings and the second ends 14b, 18b defining second openings.

In the first preferred embodiment, the first flexible bag 14 is preferably made of a permeable material, such as TYVEK®, which allows steam to pass through the first bag and sterilize the elements 12 located therein. Preferably, the second end 14b of the first flexible bag 14 is sealed along a seal line 14c after the elements 12 are located therein. Those skilled in the art will recognize from the present disclosure that the first flexible bag 14 could be made of other suitable permeable or impermeable materials, if desired, depending upon the particular application.

In the first preferred embodiment, the second flexible bag 18 is made of an impermeable material such as plastic or a multi-layer polymeric material, which protects the elements 12 inside the first bag 14 from contamination after they have been sterilized. The open second end 18b of the second bag 18 is sealed along a seal line 18c. It will be recognized by those skilled in the art from the present disclosure that the shape and size of the first and second flexible bags 14, 18 can be varied as desired, depending on the quantity of sterilized elements that are required.

Still with reference to Figs. 1 and 2, a rapid transfer port or collar 26 is attached to the first end 14a of the first flexible bag 14. The transfer port includes a sealable door 27, and is engageable with the isolation system (not shown) for transferring sterilized elements 12 into the isolation system. The transfer port 26 has an exterior surface 28 and a bore 30 extending therethrough. The exterior surface 28 has a clamp receiving area 32 with a recess 33. A groove 34 is located in proximity to the bore 30 and extends around the bore 30. The first end 14a of the first flexible bag 14 is located in the groove 34 such that the opening defined by the first end 14a is in registry with the bore 30. In the first preferred embodiment 10, the first ends 14a, 18a of the first and second flexible bags 14, 18 are located in the groove 34 such that the openings defined by the first ends 14a, 18a are in registry with the bore 30.

Those skilled in the art will recognize that various transfer port configurations could be used in conjunction with the present invention, and that the sealing of the bore 30 in the transfer port 26 could be accomplished by various other means, such as a removable seal, and the specific configuration of the transfer port 26 and the transfer port seal can be varied within the scope of the present invention. It is preferred that the transfer port 26 be constructed of a high strength material capable of withstanding repeated sterilization procedures, such as a suitable polymeric or metallic material.

Still with reference to Figs. 1 and 2, a clamp 38 is located around the flexible bag 14 proximate to the first end 14a. A portion of the flexible bag 14 is located between the clamp 38 and the recess 33 in the clamp receiving area 32 on the transfer port 26 to clamp the flexible bag 14 to the transfer port 26. Preferably, portions of the first and second flexible bags 14, 18 are located between the clamp 38 and the recess 33 to clamp the flexible bags 14, 18 to the transfer port 26. It will be recognized by those skilled in the art from the present disclosure that the clamp receiving area 32 of the transfer port 26 need not include a recess 33.

In the preferred embodiment, the clamp 38 is a band clamp of the type generally known to those of ordinary skill in the art. However, it will be recognized by those skilled in the art from the present disclosure that any type

of clamp or strap may be used to secure the first and second flexible bags 14, 18 to the transfer port 26 and provide a connection between the transfer port 26 and the first and second flexible bags 14, 18 to assist in holding the bags 14, 18 in position as sealing material 44 is placed in the groove 34, as described in detail below. The clamp also prevents the elements 12 from collecting or jamming around the connection between the transfer port 26 and the bags 14, 18.

A sealing material 44 is located in the groove 34 to encapsulate the first end 14a of the flexible bag 14 to hermetically seal the first end 14a of the flexible bag 14 to the transfer port 26. Preferably, the first ends 14a, 18a of both flexible bags 14, 18 are encapsulated in the sealing material 44 in the groove 34. In the preferred embodiment, the sealing material 44 is a hardenable liquid resin which is placed into the groove 34 and allowed to solidify around the first ends 14a, 18a of the flexible bags 14, 18. Preferably, the sealing material is a two-part epoxy. However, it will be recognized by those skilled in the art from the present disclosure that other types of adhesive systems or sealants may be used.

Referring now to Fig. 3, a second preferred embodiment of a container 110, is shown. The second preferred embodiment of the container 110 for holding elements 12 is similar to the first embodiment 10, and like

elements have been identified with the same or like reference numerals.

As shown in Fig. 3, the container 110 includes only a single flexible bag 118 which is attached to the transfer port 126 by the clamp 38 located around the flexible bag 118 proximate to the first end 118a, and a portion of the flexible bag 118 is located between the clamp 38 and the clamp receiving area 132. In the second preferred embodiment, the clamp receiving area 132 is smooth, and does not include the recess 33 as in the first embodiment 10. Preferably, the flexible bag 118 is made of a non-permeable material to protect the sterilized elements 12 in the bag. The first end 118a of the flexible bag 118 is located in the groove 34, and sealing material 44 is used to encapsulate the first end 118a of the flexible bag 118 to hermetically seal the flexible bag 118 to the transfer port 126.

It will be recognized by those skilled in the art from the present disclosure that more than two flexible bags can be used for particular applications, if desired, and that the first ends of the two or more bags can be encapsulated in a single groove 34, as described above, or in separate, spaced apart grooves on the transfer port, if desired.

A method of producing the containers 10, 110 of the present invention is also described below. One or more flexible bags 14, 18, 118 having first ends 14a, 18a, 118a

defining respective openings are provided. The first end(s) 14a, 18a, 118a is(are) located in the groove 34 in the transfer port 26, 126 which is engageable with the isolation system. The first end(s) 14a, 18a, 118a of the flexible bag(s) 14, 18, 118 is(are) encapsulated with a sealing material 44 in the groove 34 on the transfer port 26. A portion of the flexible bag(s) 14, 18, 118 proximate to the first end(s) 14a, 18a, 118a is(are) clamped to the transfer port 26, 126 to provide a load carrying attachment of the flexible bag(s) 14, 18, 118 to the transfer port 126.

This process ensures a hermetic seal being formed between the flexible bags 14, 18, 118 and transfer port 26, 126 which eliminates the possibility of contamination of sterilized elements 12 located in the flexible bags 14, 18, 118 through the interface between the flexible bags 14, 18 and the transfer ports 26, 126.

The container 10 was subjected to testing which included injection of a liquid dye into a sealed container 10 in accordance with the present invention. The assembly was manipulated such that the dye came in full contact with the connection area between the flexible bags 14, 18 and the transfer port 26. A container would pass the test when no dye could be found outside of the container after subjecting the bag to various conditions. Containers having a simple heat seal between the bag and the transfer port or a mechanical connection eventually leaked, and were found to be unsuitable for use in connection with isolation systems.

In use, the container 10 in accordance with the first preferred embodiment is produced in accordance with the above-described method, and is used for in situ sterilization of elements 12 after they have been packaged in the first flexible bag 14. The second ends 14b, 18b of the first and second bags 14, 18 are left open, and the transfer port 26 is provided in a sealed condition, with the door 27 being hermetically sealed in a closed position. The elements 12 to be sterilized, such as vial stoppers, are placed inside the first permeable bag 14 through the opening at the second end 14b. The second end 14b is then sealed along seal line 14c. Alternatively, the flexible bags 14, 18 could have only the first end 14a open. The elements 12 would then be placed through and removed from the opening defined by the first end 14a, and the elements can be placed in the first end 14a of the first flexible bag 14 through the transfer port 26 prior to closing and sealing the transfer port 26. The container 10, which contains the elements 12 to be sterilized, is then moved to an area for sterilization. Sterilization can be accomplished in an autoclave by passing steam through the first permeable bag 14 to sterilize the elements 12 within the bag. The autoclave is then evacuated by a vacuum force, and the opening defined by the second end 18b of the second non-permeable bag 18 is sealed by heat sealing or other means to provide a hermetic seal 18c along the second end 18b. The

container 10 with the sterilized elements 12 can then be stored until the elements 12 are needed.

When the elements 12 are required, the transfer port 26 is attached to a port (not shown) on an isolation system, and after sterilizing the connection area between the transfer port 26 on the container 10 and the port on the isolation system, the elements 12 can be transferred into the isolation system.

Other types of sterilization procedures may be used, such as gamma irradiation. When gamma irradiation is used for sterilization, preferably the container 110 with a single non-permeable bag 18 is used to hold the elements 12. Alternatively, elements 12 which are sterilized prior to packaging can placed in the container 110 in a sterile environment.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

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CLAIMS

1. A container for holding elements which are to be sterilized prior to introduction into an isolation system having an isolated inner region, the container comprising:

a first flexible bag defining a cavity for containing the elements, the flexible bag including a first end defining a first opening for removing the elements from the flexible bag;

a transfer port being engageable with the isolation system for transferring elements into the isolation system, the transfer port having an exterior surface which includes a clamp receiving area, and a bore extends through the transfer port and the exterior surface, a groove being located on the transfer port proximate the bore and which extends around the bore, the first end of the first flexible bag being located in the groove such that the first opening is in registry with the bore;

a clamp located around the flexible bag proximate the first end, a portion of the flexible bag being located between the clamp and the clamp receiving area on the transfer port to clamp the flexible bag to the transfer port; and

sealing material located in the groove to encapsulate the first end of the flexible bag to hermetically seal the flexible bag to the transfer port.

2. The container of claim 1 further including a second flexible bag having a first end defining a first opening of the second bag, the first flexible bag being located inside the second flexible bag, the first ends of the first and second flexible bags being encapsulated in the sealing material in the groove such that the first openings of the first and second bags are in registry with the bore.

3. The container of claim 2 wherein the first flexible bag is vapor permeable and the second bag is impermeable.

4. The container of claim 2 wherein the first and second flexible bags include second ends defining second openings for placing the elements in the cavity, the opening defined by the second end of the first flexible bag being sealed after the elements are placed in the cavity.

5. The container of claim 1 wherein the first flexible bag includes a second end defining a second opening for placing the elements in the cavity, the opening defined by the second end of the first flexible bag being sealed after the elements are placed in the cavity.

6. The container of claim 1 wherein the sealing material comprises a hardenable liquid resin.

7. A method of producing a container for holding sterilized elements, the container including a transfer port for connection to an isolation system, comprising the steps of:

providing a flexible bag having a first end defining a first opening;

encapsulating the first end of the flexible bag with a sealing material in a groove in a transfer port which is engageable with the isolation system; and

clamping a portion of the flexible bag proximate to the first end to the transfer port.

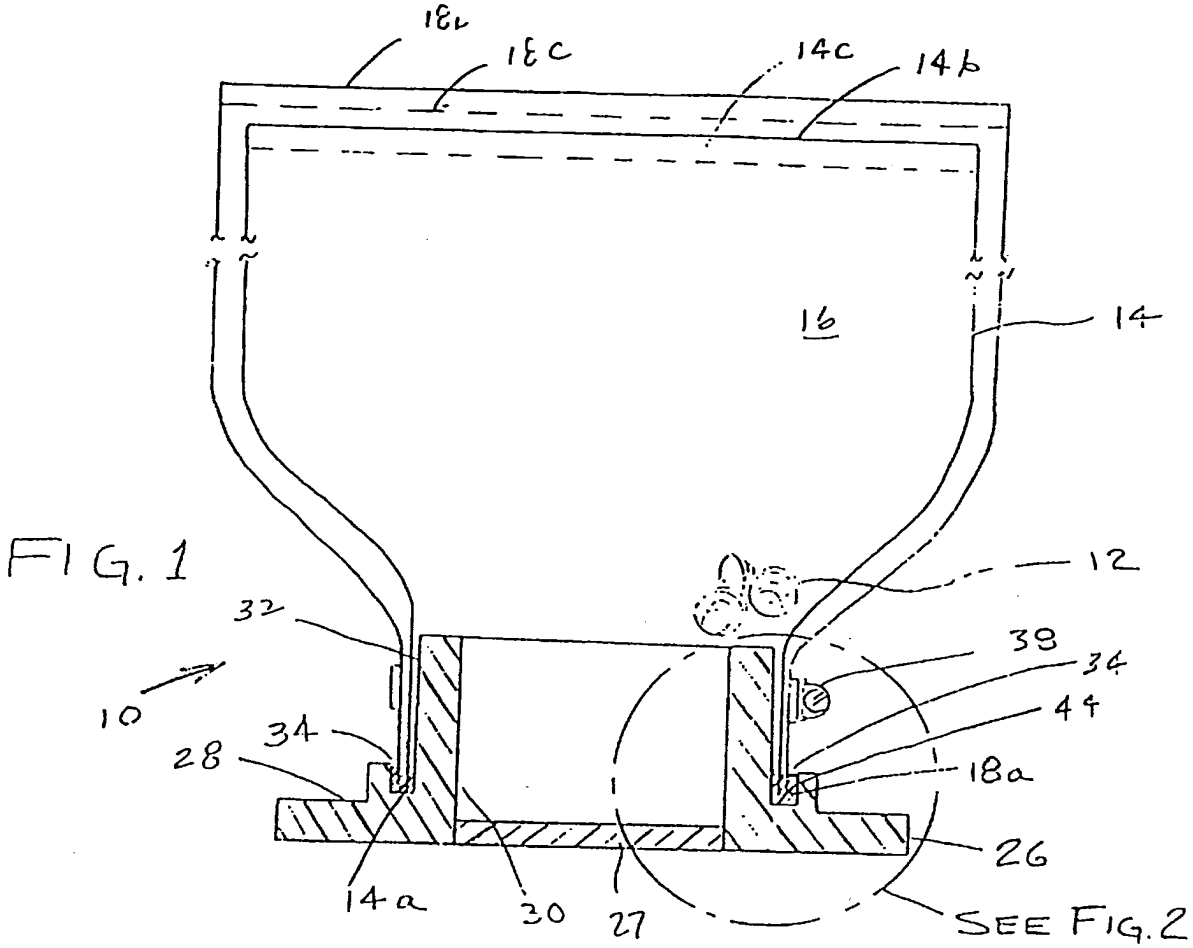

FIG. 1

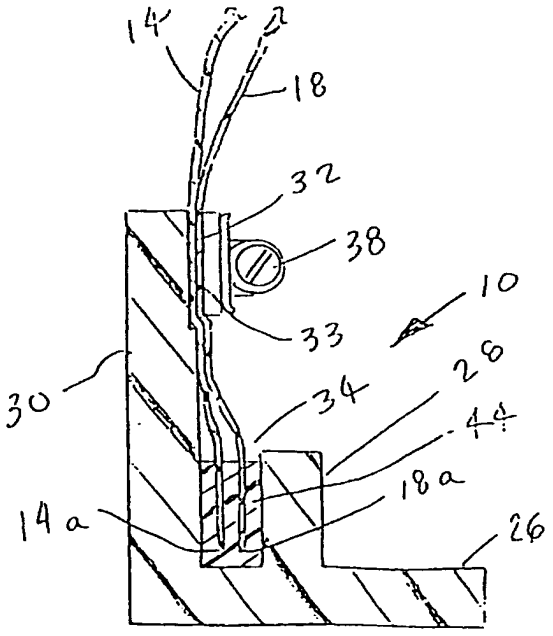

FIG. 2

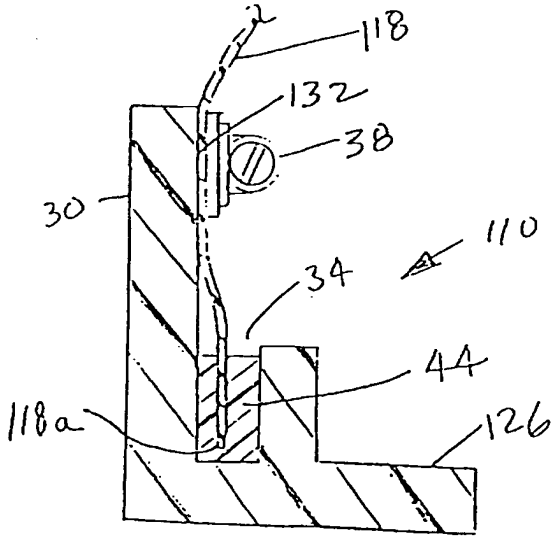

FIG. 3

PCT/US97/12472

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B65D 33/16

US CL :53/434; 383/33, 37, 41, 93; 422/294; 493/212

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 53/434; 383/33, 37, 41, 80, 93; 422/294; 493/212, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2,173,288 A (SHAPIRO) 19 September 1939	
A	US 3,647,386 A (GILFORD) 07 March 1972	
A	US 3,656,668 A (LIEBERTZ) 18 April 1972	
A	US 4,974,393 A (RICH ET AL.) 04 December 1990	
A	US 4,696,840 A (MCCULLOUGH ET AL.) 29 September 1987	
A	US 5,501,525 A (COX ET AL.) 26 March 1996	
A	US 5,636,871 A (FIELD) 10 June 1997	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 SEPTEMBER 1997	10 OCT 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer For STEPHEN P. GARBE Telephone No. (703) 308-1207

Sheila Veney
Paralegal Specialist
Group 3200

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